

BEFORE THE IOWA BOARD OF PHARMACY

RE: Pharmacy License of HY-VEE PHARMACY 1068 License No. 811 Respondent	CASE NOS. 2018-139 & 2018-140 COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER
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COME NOW the Iowa Board of Pharmacy ("Board") and Hy-Vee Pharmacy 1068 ("Respondent"), 800 N Second St, Cherokee IA 51012, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of these cases pursuant to Iowa Code chapters 17A, 155A, and 272C (2018), and 657 IAC chapter 36.

A. STATEMENT OF CHARGES

COUNT I

2018-139

FAILING TO COMPLY WITH MONTHLY INSPECTION REQUIREMENTS

1. Respondent is charged with failing to perform monthly inspections and maintain monthly inspection reports as mandated by 657 IAC 13.9(5) and 13.23(4), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT II

2018-140

VIOLATING BOARD ORDER

2. Respondent is charged with violating a lawful order of the board, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(9).

COUNT III

2018-140

FAILING TO PROPERLY RECORD PSEUDOEPHEDRINE SALES

3. Respondent is charged with failing to record the name or unique identification of the individual who approved dispensing of a pseudoephedrine product in violation of 657 IAC 100.3(1)"f", and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

B. FACTUAL CIRCUMSTANCES

4. Respondent's license is currently on probation pursuant to a Settlement Agreement and Final Order in case number 2015-110.

2018-139

5. Respondent serves as the managing pharmacy for Hy-Vee Clinic Pharmacy 3028, which is a telepharmacy site located in Marcus.

6. In November 2018, Hy-Vee Clinic Pharmacy 3028 underwent a routine inspection which revealed the following deficiencies:

- a. Neither Respondent nor the telepharmacy site had records available for the required monthly inspections. The monthly inspection records were available at a later date at the telepharmacy site.
- b. Some of the monthly inspection reports did not include an audit and reconciliation of controlled substances perpetual and physical inventories.
- c. Some of the monthly inspection records did not show monthly audits of the electronic entry system.
- d. Some of the monthly inspection reports did not show verification of proper function and retention of the video recording system.

2018-140

7. As a condition of probation, Respondent is required to perform monthly audits of its controlled substances and to comply with all state and federal laws and regulations governing the practice of pharmacy.

8. Respondent did not perform monthly audits of its controlled substances in July or August 2018.

9. A review of the monthly audits revealed several discrepancies, including the inventory reported being different from the inventory on the shelves, inventory adjustments being made without explanation, improperly filed invoices for a controlled substance, and variances for several controlled substances.

10. Respondent's pseudoephedrine sales records were not recorded using the unique identification for the individual making the sale.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

11. The Board has jurisdiction over the parties and the subject matter of this proceeding.

12. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

13. Execution of this Order constitutes the resolution of a contested case. Respondent has a

right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

14. Respondent acknowledges that it has the right to be represented by counsel on this matter.

15. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

16. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

17. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

18. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

19. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

20. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

21. Respondent's license is hereby placed on **PROBATION** for a period of three (3) years, subject to the following terms:

- a. Within thirty (30) days of this Order, Respondent shall pay a civil penalty in the amount of ten thousand dollars (\$10,000). The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.
- b. Within thirty (30) days of this Order, Respondent shall correct all deficiencies identified in the inspection report dated November 19, 2018, and shall submit evidence of corrective actions, including updated policies and procedures when applicable, to the Board.

- c. Within one hundred and twenty (120) days of this Order, Respondent shall cease serving as the managing pharmacy for the telepharmacy site located in Marcus. While on probation, Respondent is prohibited from serving as a managing pharmacy for a telepharmacy site.
- d. Respondent shall perform monthly self-inspections and shall submit the self-inspection reports to the Board after each inspection. Within thirty (30) days of this Order, Respondent shall submit a proposed template for the monthly self-inspections to the Board for approval. Monthly inspections shall commence upon Board approval of the monthly self-inspection template.
- e. Respondent shall conduct a monthly physical inventory for all Schedule II controlled substances and for twenty-five (25) Schedule III-V controlled substances that are high risk for diversion. The monthly physical inventory must be reconciled within seven (7) days of taking the inventory.
- f. A copy of each monthly self-inspection report and documentation of each monthly inventory/reconciliation shall be submitted to the Board by the 7th day of the month following the month of inspection (e.g., January documentation shall be submitted to the Board no later than February 7th).
- g. Respondent shall notify the Board within three (3) business days of any change in the pharmacist in charge.
- h. Respondent shall provide a copy of this Order to all current and future employees of the pharmacy for the duration of probation, including any district managers and store managers that have supervisory authority over the pharmacist in charge.
- i. Respondent shall appear before the Board upon request for purposes of evaluating performance of the probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- j. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- k. Any documentation required to be submitted shall be emailed to Amanda.Woltz@iowa.gov by the specified deadline unless otherwise directed.

22. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC chapter 36.

By the signature below, Kristin Williams acknowledges s/he is the Senior Vice President, Chief Health Officer for Respondent and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

3/11/2019
Date

Kristin Williams
HY-VEE PHARMACY 1068
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of March, 2019.

Susan Truitt
Chairperson
Iowa Board of Pharmacy